8EHQ-0798-14229S

TSCA HEALTH & SAFETY STUDY COVER SHEET

TSCA CBI STATUS:

-CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)

Clearly mark the confidential information with bracketing and check the box in the appropriate section (☐ *Contains CBI*). Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

1.0 SUBMISSION TYPE *X- Contains CBI*

☐ 8(d) **X 8(e)** ☐ FYI ☐ 4 ☐ OTHER: Specify_____

XX- Intial Submission -Follow-up Submission - Update ☐ Final Report Submission

Previous EPA Submission Number or Title if update or follow-up: Docket Number, if any: #

☐ continuation sheet attached

2.1 SUMMARY/ABSTRACT ATTACHED (may be required for 8(e): optional for §4, 8(d) & FYI) X - YES ☐ NO	**2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID** Cert# P 917006746 98-2-16	**2.3 FOR EPA USE ONLY**

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY *–Contains CBI*

Reported Chemical Name (specify nomenclature if other than CAS name):

CAS#: N/A

COMPANY SANITIZED

Purity _____%

X – Single Ingredient

☐ Commerical/Tech Grade

☐-Mixture Confidential Information Has Been Sanitized *Trade Name:* _____ *Common Name:* Urazol – Chemical Class

4.0 REPORT/STUDY TITLE *- Contains CBI*

Letter report of Developmental Toxicity Screening in Rats after Oral Administration, Study # T7062090

☐ Continuation sheet attached

5.1 STUDY/TSCATS INDEXING TERMS

[CHECK ONE]

HEALTH EFFECTS (HE): X ENVIRONMENTAL EFFECTS (EE):_____ ENVIRONMENTAL FATE (EF):_____

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

STUDY TYPE: TOX	SUBJECT ORGANISM (HE, EE only): RATS	ROUTE OF EXPOSURE (HE only): Food	VEHICLE OF EXPOSURE (HEonly)_
Other: Developmental	Other:_____	*Other:* _____	
Other:			

6.0 REPORT/STUDY INFORMATION ☐ *Contains CBI* - Study is GLP

Laboratory Bayer Toxicology, Wuppertal, Germany Report/Study Date: 7/1/98

Source of Data/Study Sponsor (if different than submitter) Bayer AG Number of pages

☐ continuation sheet attached

7.0 SUBMITTER INFORMATION ☐ *Contains CBI*

Submitter: Donald W. Lamb, Ph.D Title: V. P., Prod. Safety & Reg. Affrs Phone: 412-777-7431

Company Name: Bayer Corporation Company Address: 100 Bayer Road

Pittsburgh, PA 15205-9741 Submitter Address (if different): _____

Technical Contact: Donald W. Lamb, Ph.D Phone: (412)777-7431

☐ continuation sheet attached

8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS ☐ *Contains CBI*

This compound is a developmental herbicide. – Purpose of the study : Screening study to investigate for a developmental potential.

☐ continuation sheet attached

Submitter Signature: Donald W Lamb **Date:** 7/21/98

8EHQ-98-14229

88980000196S

9.0 CONTINUATION SHEET

TSCA CBI STATUS:

- CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)

Clearly mark the confidential information with bracketing and check the box in the appropriate section (*☐ Contains CBI*). Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

Submitter Tracking Number/Internal ID

P917006746
98-2-16

2.1 Summary/Abstract Attachment

Confidential Information Has Been Sanitized

Discussion of Reported Effects:

Inseminated Wistar rats were daily treated orally by gavage with 100, 300 or 1000 mg /kg body weight from day 6 to day 19 p.c.The substance was formulated in 0.5 % carboxymethylcellulose in demineralized water. The group size was 7 at 100 mg/kg (two females with implantation sites) or 4 at 300 and 1000 mg/kg. The fetuses were delivered by cesarean section on day 20 p.c. Investigations were performed on the general tolerance of the test compound by the females as well as on its effects on intrauterine development (pregnancy rate, number of fetuses and resorptions, external findings in the fetuses, fetal weight and fetal skeletal malformations and variations (wavy ribs only)).

Two animals of the 300 mg/kg group and all animals of the 1000 mg/kg group were found dead or were killed for human reasons between days 7 and 13 p.c.
At the 300 mg/kg level and above the animals showed severely decreased feed intakes and correspondingly reduced feces as well as severe body weight loss after start of treatment, sunken flunks or piloerection. Increased water consumption and increased urination occurred at the 100 mg/kg level and above.
Gross necropsy showed pale, enlarged, soft kidneys or pale liver, respectively, in the 300 mg/kg group. At the necropsy of the animals in the 1000 mg/kg group only signs of general autolysis and no specific changes were found.

Due to the early death of all animals in the 1000 mg/kg group (see above) evaluation of the reproduction parameters was not possible in this group.
The pregnancy rate was unaffected and the resorption rate did not reveal treatment related effects at levels up to and including 300 mg/kg.
Fetal weight was severely decreased at the 300 mg/kg level.
Furthermore, the skeletal evaluation revealed malformations (dysplasia of forelimb long bones and scapula) and variations (wavy ribs) in a high incidence (72 % of fetuses affected) in the 300 mg/kg group.
Two fetuses (7 %, one affected litter) of the 100 mg/kg group also showed wavy ribs. The incidence of this finding in the 100 mg/kg group was, however, within the normal scattering range for the strain of rats used and was thus considered incidental.

Conclusions:

In this study, decreased fetal weights as well as skeletal malformations and variations occurred at the 300 mg/kg level.
Final evaluation of these findings, however, should be based on a succeeding guideline study and not on the limited data available from this screening study.